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PATENT  
2801-0202P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Johannes H. M. SCHELLENS et al. Conf.: 8475

Appl. No.: 09/988,285 Group: 1632

Filed: November 19, 2001 Examiner: P. PARAS, JR.

For: A METHOD OF IMPROVING BIOAVAILABILITY OF  
ORALLY ADMINISTERED DRUGS, A METHOD OF  
SCREENING FOR ENHANCERS OF SUCH  
BIOAVAILABILITY AND NOVEL PHARMACEUTICAL  
COMPOSITIONS FOR ORAL DELIVERY OF DRUGS

INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION AFTER FILING OF AN APPLICATION  
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE  
OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DEC 18 2003

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

**I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

**II. COPIES (check at least one box)**

- a.  This application was filed before June 30, 2003. Accordingly, submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b.  This application was filed on or after June 30, 2003. Accordingly, copies of cited U.S. patents and patent application publications therefore are not included. Copies of foreign patent documents and non-patent literature are included.

- c.  Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

**III. CONCISE EXPLANATION OF THE RELEVANCE**  
(check at least one box)

- a.  **DOCUMENTS IN THE ENGLISH LANGUAGE**

The patents, publications, or other information listed on the attached PTO 1449 are in the English language and therefore, do not require a statement of relevancy.

- b.  **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

- c.  **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

- d.  **OTHER**

The following additional information is provided for the Examiner's consideration.

An English abstract is provided for WO 00/7605 A1.

FEES

- IV.  THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b) :  
(check one box)
- a.  within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (*This section is not to be used with RCE's.*)
- b.  within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c.  concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- d.  before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required.  
In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
- V.  THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c) :  
(check one box)
- before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).
- a.  No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).  
*or*
- b.  See the statement below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a.  each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b.  no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
- c.  Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

- A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

  
By \_\_\_\_\_  
Gerald M. Murphy, Jr., #28,977

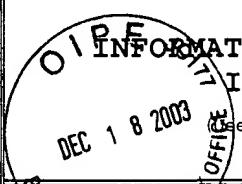
P.O. Box 747  
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GMM/las  
2801-0202P

- Attachment(s) :  PTO-1449  
 Documents  
 Foreign Search Report  
 Fee  
 Other:

(Rev. 09/30/03)

Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(See several sheets if necessary)

ATTY. DOCKET NO.  
2801-0202PAPPLICATION NO.  
09/988,285

## APPLICANT

Johannes H. M. SCHELLENS et al.

## FILING DATE

November 19, 2001

## GROUP

1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	KIND	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	US 5,604,237	A	1997-02-18	Dumaitre et al.			
	US 6,004,927	A	1999-12-21	Benet et al.			
	US 6,469,022	B1	2002-10-22	Schellens			
	US 6,521,635	B1	2003-02-18	Bates et al.			
	US 5,567,592	A	1996-10-22	Benet et al.			
	US 5,663,179	A	1997-09-02	Dumaitre et al.			
	US 5,786,344	A	1998-07-28	Ratain et al.			
	US 5,958,937	A	2899-09-01	Hausheer et al.			
	US 6,028,054	A	2000-02-22	Benet et al.			
	US 6,248,891	B1	2001-06-09	Sharp et al.			

## FOREIGN PATENT DOCUMENTS

	Office	DOCUMENT NUMBER	Kind	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION/ABSTRACT	
								YES	NO
	WO	00/07605	A1	2000-02-17	WIPO			w/Abst.	
	EP	0 098 098	A2	1984-01-01	EUROPE				
	EP	0 494 623	A1	1992-07-15	EUROPE				
	WO	92/12132	A1	1992-07-23	WIPO				
	WO	99/40110	A1	1999-08-12	WIPO				
	WO	98/53811	A1	1998-12-03	WIPO				
	WO	99/65493	A1	1999-12-23	WIPO				
	WO	97/15269	A2	1997-05-01	WIPO				
	WO	94/01408	A1	1994-01-20	WIPO				

## OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)

	Rabindran et al., Cancer Research, 58, 5850-5858, Dec. 15, 1998
	Hazlehurst et al., Cancer Research, 59, 1021-1028, March 1, 1999
	B. Kuska, Journal of the National Cancer Institute, Vol. 91, No. 5, 402-404, March 3, 1999
	Ross et al., Journal of the National Cancer Institute, Vol. 91, No. 5, 429-433, March 3, 1999

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449  O I INFORMATION DISCLOSURE CITATION IN AN APPLICATION  Use several sheets if necessary)				ATTY. DOCKET NO. 2801-0202P	APPLICATION NO. 09/988,285		
				APPLICANT Johannes H. M. SCHELLENS et al.			
				FILING DATE November 19, 2001	GROUP 1632		
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL	DOCUMENT NUMBER	KIND	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
<b>FOREIGN PATENT DOCUMENTS</b>							
Office	DOCUMENT NUMBER	KIND	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION
WO	96/11007	A1	1996-04-18	WIPO			YES      NO
<b>OTHER DOCUMENTS</b> (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.)							
K. Miyake et al., Cancer Research, January 1, 1999, Vol. 59, pp. 8-13.							
Allikmets et al., Cancer Research, 58, 5337-5339, Dec. 1, 1998							
Doyle et al., Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 15665-15670, Dec. 1998							
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Denny et al., J. Med. Chem. 1987, 30, 658-663							
Sparreboom et al., Anticancer Drugs, 10(8) : 719-728, Sept. 1999							
de Bruin et al., Cancer Letters, 146 (1999) 117-126							
Hyafil et al., Cancer Research, 53, 4595-4602, Oct. 1, 1993							
Karato et al., Journal of Clinical Oncology, Vol. 11, No. 10, pp. 2030-2035, Oct. 1993							
Slischenmyer et al., J. Natl. Cancer Inst., Vol. 85, No. 4, pp. 271-291, 1993							
Sikic et al., 12 <sup>th</sup> Bristol Myers Squibb Nagoya International Cancer Treatment Symposium, October 4-5, 1996, Nagoya, Japan, pp. S13-S19							
Sparreboom et al., Proc. Natl. Acad. Sci. USA, Vol. 94, 2031-2035, March 1997							
Rabindran et al., Proceedings of the American Association for Cancer Research-Annual Meeting, March 1999, Vol. 40, pp. 315-316, Abstract #2093.							
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if citation considered; whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							